NFPA®
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

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Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

Re: Docket No. 1998N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; 69 Federal Register 35380; June 24, 2004

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA submits the following comments on the request referenced above. Our comments will follow the same format as the FDA 2004 Work Plan published on the Center for Food Safety and Applied Nutrition (CFSAN) web site.

I. Assuring Food Safety and Security

1.1 Regulations

NFPA notes that some of the "A" priority list for 2004 as related to the implementation of the Bioterrorism Act have been completed, but much remains undone and is likely to continue as a top priority for 2005. Of particular interest to NFPA is the publication of the final rule for the establishment and maintenance of records (1.1.5), including publication of FDA procedures to protect sensitive business information, the Joint FDA and

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CBP plan for increasing integration of time frames (1.1.9), and a resolution to the interim final rules on prior notice that will allow legitimate product research and development to continue within the U.S. by accommodating the import of product samples. This is a top priority issue for industry that has yet to be addressed by FDA and, consequently, has the potential of diverting this type of commercial activity to other markets. NFPA is optimistic, a solution will be identified in 2004 but Amendment to the interim final rule for prior notice should be an "A" priority.

In publishing the final rule to implement the Product Detention regulations, FDA announced that it would propose to define the criteria for determining what constituted "serious adverse health consequences" for purposes of the detention rules. NFPA recommends FDA elevate this to an "A" priority for proposal and completion of a final rule in 2005.

NFPA notes that 2004 "B" priorities identified the development "Good Importer Practices" that would help food importers comply with new Bioterrorism regulations. NFPA recommends that this should be elevated to an "A" priority and should include as much information as possible on FDA/CBP handling of information and products at the border as well as "risk based" determinations for inspections that will assist importers to facilitate compliance and minimize disruptions to trade.

1.2 Laboratory Preparedness

NFPA recommends that operation of the Food Emergency Response Network (1.2.1) and the coordination of food security and counter-terrorism issues with federal, state, and local governments and other organizations (1.2.11) be continued as an "A" priority into 2005 and other 2004 "A" priority items not completed in 2004 be carried forward for completion in 2005.

1.3 Domestic Inspections

NFPA supports continuation of an "A" priority for the inspection of domestic firms that produce "high-risk" foods. An evaluation of the previous years inspection results should be used to further focus future inspections on critical areas of concern.

1.4 Imports and Foreign Inspections

NFPA supports continuation of import surveillance as an "A" priority. FDA should establish as an "A" priority the publication of a final rule establishing requirements pertaining to sampling services and private laboratories used in connection with imported food subject to an FDA enforcement action (Docket No. 2004N-0184). Comments filed in response to the proposed action should also be taken into account.

NFPA further suggests that the agency explore partnership activities that may allow for FDA consideration of private laboratory results as a basis for import acceptance/rejection. FDA recognizes that private laboratories can play an important role in ensuring that imported food products reaching consumers meet FDA requirements and help prevent noncompliant or violative products from entering the market. Use of private laboratory results as a basis for entry decisions would simply expand the scope of proposed rules for use of private laboratories to test samples of imported food in connection with an FDA enforcement action.

1.5 Seafood Safety

With regard to the CFSAN's FY 2004 work plan, NFPA notes and appreciates the FDA efforts made to issue the consumer advisory on methyl mercury in seafood, which we believe delivered an accurate assessment of the overall benefits of fish consumption, as well as the risk for some women and children from consumption of certain species of fish. We also recognize the interagency cooperation required to develop the advisory with the Environmental Protection Agency.

NFPA also notes that CFSAN intends to publish a progress report that will further describe activities and actions taken to accomplish other FY 2004 priorities. We trust that progress has been made on each of the 2004 priorities, and would encourage completion of the "A" list goals – particularly continuing efforts to control *Vibrio* spp. in raw molluscan shellfish. Based on industry feedback, we also anticipate that FDA's evaluation of seafood HACCP program performance would reflect an increase in compliance rate, and provide further detail on areas of the program that require refinement or improvement.

For FY 2005, NFPA would recommend focus on the following areas for "A" list consideration:

- Continued emphasis on import surveillance, as over 70% of seafood consumed in the U.S. is now imported.
- Continue surveillance on imported shrimp for chloramphenicol, while also assessing risk for low-level detection in non-cultured products and determination of the origins of such levels.
- Use risk assessment tools to model risk from *Clostridium botulinum* growth and toxin formation in seafood products packed in reduced oxygen packaging. Assessment inputs should include not only growth parameters, but also likelihood of incidence in certain products either from natural flora, or by recontamination.

- Revise and publish a 4th edition of the Fish and Fishery Products Hazards and Controls Guide. Seek input from regulatory and industry stakeholders to provide the most recent advances in science-based control procedures for ensuring the continued safe production of seafood products for inclusion in the new edition.
- If not completed in FY 2004, elevate to "A" list priority efforts to improve existing guidance on proper on-board handling for the fishing industry that harvest scombroid species.

1.6 Fruits and Vegetables

NFPA congratulates FDA for finalizing the first edition of the Juice HACCP Hazards and Controls Guide. This document greatly assists the juice industry in achieving compliance with the juice HACCP regulations. Likewise, NFPA recommends FDA elevate the 2004 "B" priority (1.6.12) to provide assistance to the California Department of Health Services on production of the video on safe juice processing. If properly constructed, the video will provide a valuable training tool for federal and state regulators, as well as for industry.

NFPA recommends that, in conjunction with its review of the Good Manufacturing Practice Regulations, FDA establish as an "A" priority the publication of guidance to the industry on the use of alternative temperature recording devices in lieu of the mercury in glass thermometer for used low-acid foods packed in hermetically sealed containers.

The Good Manufacturing Practices-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, 21 CFR Part 113 requires that temperatures in all retort systems be measured using a mercury-in-glass thermometer. For Aseptic systems, a provision is provided to allow for "an equivalent temperature–indicating device, such as a thermocouple-recorder."

Because of the health and regulatory consequences of the use of mercury, the food industry is interested in minimizing sources of mercury in the processing plant. In addition, because of the possible limited source of thermometer grade glass, reference grade mercury-in-glass thermometers may become more difficult to obtain. The ongoing automation of the industry, with the potential to enhance retort operations utilizing accurate electronic sensors, adds to the need to provide for the use of alternative temperature measuring devices in lieu of the use of mercury-in-glass thermometers.

1.7 Listeria

NFPA supports an "A" priority for FY 2005 for completion of consideration of the Citizen Petition to amend 21 CFR Part 109 to establish a regulatory limit for *Listeria monocytogenes* in foods that do not support its growth (Docket No. 2003P-0574). We also recommend FDA set an "A" priority for developing guidance on control of *Listeria monocytogenes* in facilities producing ready-to-eat products (1.8.3).

1.9 Cooperative Programs

NFPA urges FDA to reinstitute funding for the Food Chemicals Codex program within the Institute of Medicine of the National Academies of Science. The FCC plays a vital role in establishing food grade specifications and purity for food colors, flavors, functional food components, and virtually all the direct food additives and some indirect food additives such as enzymes and processing aids in use today. NFPA and NFPA Member companies depend on, and extensively use, the FCC as the authoritative source in decisions regarding the production and purchase of the food ingredients covered. The FCC is also extremely important for facilitating US trade and establishing a critically needed reference for food grade specifications and purity in international trade.

The possible elimination of the FCC and the Committee on Food Chemicals Codex also raises questions over the standing and applicability of a number of FDA's current regulations. The FCC is cited by the FDA as the reference for food grade specifications of food additives in the Code of Federal Regulations at 21 CFR §170.30(h) and is included in the individual listings of substances affirmed as Generally Recognized as Safe (GRAS) in 21 CFR §184. We consider, and FDA clearly indicates, that FCC standards are legal standards for marketing numerous GRAS food additives and provide the only scientifically valid vehicle for establishing safety and purity standards for new products in the U.S. As such, ending the FCC would have practical implications on the specifications used by ingredient manufacturers and food processors, as well as FDA current and future rulemaking.

NFPA strongly encourages FDA's continued funding to keep the FCC current and to provide continuity for the Committee on Food Chemicals Codex that oversees this publication. An added benefit is the leveraging of FDA resources to provide current food grade specifications for GRAS food ingredients.

Likewise, NFPA endorses continued funding be made available to the FAO/WHO Joint Expert Committee on Food Additives (JECFA) to provide for timely risk assessment review of selected food additives and contaminants.

1.10 Chemical Contaminants, Pesticides and Other Hazards

For 2005 NFPA recommends FDA move the following items from "B" priority to "A" priority:

- Update the pesticides CPG to bring it into line with FQPA (1.10.12);
- Issue final generic "channels of trade" guidance (1.10.20); and
- Develop for the internet the FDA Pesticide Monitoring data and summary information as required by the Pesticide Monitoring Improvement Act (1.10.14).

Other items in this section should be retained as a "B" priority for future action as agency resources permit.

1.12 Game Meat

Identification of manufacturers and processors of game meats and game meat products should be initiated as an "A" priority for 2005 to ensure that these processors have complied with the requirements for registration of food facilities.

1.13 Food Allergens

NFPA recommends FDA establish as an "A" priority the review of Public Law 108-282. Title I of the law is the Minor Use and Minor Species Animal Health Act. Title II is the Food Allergen Labeling and Consumer Protection Act. This should be an "A" priority with respect to food allergen labeling and the agency should initiate appropriate action either to incorporate changes into the food labeling regulations or to revise guidance documents (e.g., Compliance Policy Guide Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens) as appropriate. This would amend and elevate the current "B" priority goal 1.13.5. Develop proposed rule for the labeling of the most common allergens to an "A" priority. NFPA further recommends that CFSAN develop a science-based allergen threshold so that food companies (1) can establish operational cleaning standards, and (2) can know when an ingredient containing a trace level of protein derived from an allergen must comply with the labeling requirements under the new bill.

NFPA recommends an "A" priority for the development of guidance for control of allergens in FDA-regulated plants producing products containing the "big 8" allergens identified by the agency and products that do not contain such allergens, particularly when the products share production lines.

II. Improving Nutrition and Dietary Supplement Safety

2.1.6 Enforcement/Compliance

NFPA supports the continuation of enforcement activities related to inappropriate labeling of conventional foods as an "A" priority for CFSAN.

III. Assuring Food and Cosmetic Safety

3.1 Food and Color Additives Review

3.1.1 Review of Industry Submissions

NFPA recommends FDA maintain the current "A" priority list from 2004 into 2005 and update 3.1.1.b for the petition receipt cohort of FY 2004 and make provision for a completion date for any remaining FY 2003 petitions.

3.1.2 Protecting and Promoting Public Health

Retain current "A" list items and, if resources permit, consider work on "B" priority items 3.1.2.e (Develop a *Federal Register* proposal extending exclusion from Environmental Assessment to additional categories of Agency action on food and color additives), 3.1.2.f (Amend 21 CFR section 178.1010 to accommodate partial transfer of this regulation to EPA as provided for in the Food Quality Protection Act) and 3.1.2.i (Continue to make additional final revised Redbook Chapters available on the FDA website). Retain other "B" priority items for possible action as resources permit.

3.1.3 Improve Efficiency/Responsiveness

Retain current "B" priority items and initiate work if resources are available.

3.1.4 Enforcement/Compliance

Retain current item as an "A" priority if not completed in 2004.

IV. Assuring Food Safety: Crosscutting Areas

4.1 International

Continue the current "A" list priority items into 2005.

4.2.1 Codex Committees and Working Groups

NFPA strongly supports CFSAN's continued strong leadership in Codex Alimentarius and agrees with the list of designated "priority" committees, noting that the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology will reconvene in 2006, but work must begin in 2005 to identify priority issues and U.S. positions, including new leadership for this work (considering pending retirements). In addition to the listed items which NFPA supports as an "A" priority, there is a need to ensure FDA has the funding to do extensive outreach before the Codex meetings to educate - especially in developing countries - on the issues and the science behind the U.S. positions.

NFPA also notes that more attention needs to be focused on the work (or lack thereof) of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This committee is considering critical science-based issues on which achieving international consensus as quickly as possible is imperative. For example, this committee is considering scientific substantiation for health claims and fortification with vitamins and minerals, as well as standards for foods for special populations. These foods are increasingly important in international trade, yet this was the single Codex Committee that adopted NO new standards for adoption in the past 3 years. The U.S. government must provide leadership to ensure that CCNFSDU becomes an effective and productive venue to address these important issues.

NAFTA TWGs participation in Technical Working Groups (TWGs) with Canada and Mexico is an "A" priority. The Agency must take a lead role on food initiatives to make more effective use of the TWGs as a venue to address ongoing cross border issues directed towards barriers, policy, procedures, and standards in order to facilitate trade under NAFTA. Of particular importance in 2005 will be new nutrition labeling requirements in both Canada and Mexico.

4.2.2 Trade Negotiations

Trade Negotiations. FDA's participation in the related Sanitary and Phytosanitary (SPS) negotiations should remain a top priority. However, separate SPS committees have been created under the new FTAs that will also demand priority attention from FDA. Used effectively, these committees can provide excellent forums to resolve critical trade issues.

NFPA notes that in 2004 participation in the FTAA negotiations was only a "B" priority for FDA. Because of the importance of the Western Hemisphere as a market for U.S. food companies, and because of the proliferation of SPS barriers in that market, a stronger commitment from FDA will be necessary as FTAA negotiations move forward.

4.2.3 Export Certificates

NFPA notes that the ongoing efforts under AFDO with respect to export certificates have been continued beyond the 2004 mandate with the specific charge of building the website with information from both domestic and international sources. While the USDA Foreign Agriculture Service (FAS) has agreed to assume the leadership for the data collection, NFPA strongly believes that FDA's continued leadership within AFDO on this specific project is critical to its success. NFPA agrees that this can remain a "B" priority for FDA.

4.3 Food Biotechnology

Retain all priorities that are not completed in 2004 into FY 2005.

4.5 Economic Based Regulations

NFPA commends the agency for recognizing the need to address some economic based regulations, specifically regulations dealing with food standards of identity. Unfortunately, the current items listed as "A" priorities for 2004 have yet to be acted upon and, in any case, deal only with either "filing a report to Congress" or "publishing a proposal." There are no listings for "publish a final rule amending the standard."

There is no purpose in publishing additional proposals if the agency has no plans nor intention of completing the process with the publication of a final rule either amending the proposal or providing a sound set of reasons, based on comments filed in response to the proposal, for terminating the proposed action. Indeed, the agency has numerous proposals which have yet to be completed, and additional Citizen Petitions to amend standards of identity which have yet to be acted upon. So far, the primary response has been to "wait ten years then contact the petitioner to see if they are willing to withdraw their petition."

Many, indeed perhaps a majority, of the petitions dealing with amendments with standards of identity were filed in conjunction with, or following the submission of, a temporary marketing permit to allow one or more firms to pack the product in the manner described in the petition with the intent of amending the standard of identity. If the

Citizen Petition is withdrawn, the temporary marketing permit is no longer valid and the firm may no longer legally pack and sell the product.

Develop a plan to review and address the current backlog of petitions related to standards of identity in a timely manner

NFPA recommends that FDA establish as an "A" priority. The development of a timetable to get requested actions underway, with priority for petitions addressing outstanding NLEA issues for products currently packaged under temporary marketing permits.

We suggest that CFSAN review its backlog list of pending petitions to amend standards of identity (especially those associated with temporary marketing permits) and add these to the "A" list for 2004. NFPA's June 4, 1989 petition to amend the canned salmon standard of identity to include the style "skinless, boneless" should be included in that list (Docket No. 88P-0190/CP02). CFSAN should develop a plan to review and complete these items in a timely manner. FDA successfully initiated and completed a notice detailing labeling requirements for catfish in one year. NFPA is encouraged by this accomplishment that more timely completion of actions on pending petitions is possible.

NFPA requests FDA initiate rulemaking to revise the outdated standard of identity for canned tuna as requested in a Citizens Petition (Docket No. 94P-0286) to replace the current press cake weight requirement with drained weight requirements and to incorporate any other changes that may be deemed necessary.

NFPA also requests FDA consider as an "A" priority item for 2005 the 1989 citizens petition (Docket # 88P-0190/CP02) to amend the canned salmon standard of identity at 21 CFR 161.170. NFPA understands that FDA is currently evaluating its "Guiding Principles for Standards," however, until those principles are developed we feel the appropriate amendments to the canned salmon standard of identity would provide companies the opportunity to introduce innovative new products to the market under the standard that would satisfy the preferences of their consumers. Because of the development of new processing technologies and further identification of consumer desires since 1989, NFPA also advises FDA that further amendments to the petition are being considered for submission to FDA prior to 2005.

NFPA suggests two other proposed amendments to standards of identity concerning 21 CFR §145.180 canned pineapple (86P-0338) and 21 CFR 146.185 canned pineapple juice (88P-0224) be considered for completion as a final rule in 2005. NFPA's positions on these proposals were addressed in detail in NFPA's comments of July 21, 2003 to Docket No. 02N-0434, "Withdrawal of Certain Proposed Rules and Other Proposed Actions."

Issues Not Identified on the 2004 Priority List to be added in 2005

For the past several years, CFSAN priorities have included the completion of equivalence criteria which has been in an unfinished state on the "B" list. This task was apparently eliminated from CFSAN priorities in 2004 in spite of the fact that it has not been accomplished. The Codex guideline for the determination of equivalency was adopted in 2003. It should now be a simple task to complete the FDA guidance and ensure that it is consistent with international standards. NFPA believes equivalency agreements can be useful in minimizing resource needs and facilitating trade and we find it disturbing that CFSAN has not been able to publish final rules on this issue. This is a simple task that should be added to the "A" list and moved quickly to completion.

Also, in 2003 FDA indicated that "Working in concert with FDA's Office of International Programs to ensure effective communication with the Office of USTR" was on CFSAN's "B" list. At that time, NFPA recommended elevating this communication to an "A" priority for 2004. Instead, it was removed from CFSAN priorities entirely. Effective interagency communication to enable coordinated U.S. positions must be an "A" priority every year in order to effectively advance food policy in international forums, to ensure U.S. trade commitments are not compromised and to ensure that negotiations are effectively used to reduce technical barriers for U.S. food exports. NFPA is very disappointed that CFSAN no longer views interagency communication as a priority and urges better prioritization of this issue.

In 2004, FDA reopened the comments pertaining to recordkeeping requirements under the FDA Export Reform and Enhancement Act. FDA reopened these regulations in response to a petition that challenged FDA's authority. Amendment of the rule should be an "A" priority for 2005.

We appreciate this opportunity to comment on CFSAN priorities for FY 2005 and encourage FDA to consider our points as priorities are established. Please contact us if you have questions or wish to discuss our comments in more detail.

Regards,

John R. Cady

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